

REMARKS

Reconsideration of the rejections set forth in the Office Action mailed December 15, 2005, is respectfully requested. Claims 27 and 61-68 were cancelled without prejudice. Claims 19 and 54-60 remain pending in this case.

35 U.S.C. § 112

Claim 62 was rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention. Claim 62 has been cancelled without prejudice. Therefore, this rejection is now moot.

Art Rejections

Claims 19, 27, 54-56, and 61-64 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Inoue et al. "Effect of Stimulation of the Dorsal Aspect of the Cervical Spinal Cord on Local Cerebral Blood Flow and EEG in the Cat." NEUROLOGICAL RESEARCH 22(4): 386-92 (June 2000). Claims 57-60 and 65-68 were rejected as allegedly unpatentable over Inoue et al..

Claims 27 and 61-68 were cancelled without prejudice. Therefore, the rejections are now moot as to these claims.

Claim 19 requires the steps of "*inserting the elongate member ... into the subarachnoid space*" and "*advancing the electrical stimulating device cephalad and positioning the electrical stimulating device adjacent the brain stem*." (emphasis added) In contrast, Inoue teaches to

introduce the electrode into the epidural space. Inoue was concerned with electrical stimulation of the dorsal aspect of the cervical spinal cord as a potentially effective therapy for persistent vegetative patients. (See Abstract). In their studies, Inoue stimulated the spinal cord by introducing a lead type of electrode epidurally to the midline of the C2-C3 segments, an anatomy that is well below the brain stem. (See page 387, Col. 2, lines 5-7).

It is not possible to insert a device between lumbar vertebrae, low cervical vertebrae, or high thoracic vertebrae into the epidural space and advance the device cephalad such that the device could be positioned adjacent the brain stem. The epidural space terminates at the foramen magnum, where the spinal dura is adherent to the margin of the foramen magnum of the skull. As explained on page 366 of Moore, K.L., ed., CLINICALLY ORIENTED ANATOMY, 3rd ed., Williams & Wilkins, 1992, (EXHIBIT A) “[t]he spinal dura forms a long tubular sheath or *dural sac* that is free within the vertebral canal. It is adherent to the margin of the foramen magnum of the skull, where it is *continuous with the cranial dura mater*.” Because a catheter cannot be advanced beyond the foramen magnum within the epidural space, the catheter cannot reach the brain stem, which lies well above the foramen magnum.

In contrast, the sub-arachnoid space is not blocked by the foramen magnum. Therefore, a device can be inserted between lumbar vertebrae, low cervical vertebrae, or high thoracic vertebrae into the subarachnoid space, as recited in the claims, and advanced cephalad such that the device is positioned adjacent the brain stem. Therefore, Inoue et al. does not teach or suggest all of the limitations of the currently pending claims. Claims 54-60 are dependent on claim 19 and are patentable for the same reasons as applicable to claim 19. Applicants respectfully request withdrawal of the rejections and reconsideration of the currently pending claims.

Favorable action on the merits of the claims is therefore earnestly solicited. If any issues remain, please contact the applicants' undersigned representative at (949) 760-9600. The Commissioner is hereby authorized to charge any fees that may be required in connection with the filing of these documents to Deposit Account No. 50-2862.

Respectfully submitted,
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